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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,899

01/21/2004

Robert Allan Phillips

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23552 7590 04/07/2008  
MERCHANT & GOULD PC  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

EXAMINER

LEE, YUN HAENG NMN

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

04/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/761,899	<b>Applicant(s)</b> PHILLIPS, ROBERT ALLAN	
	<b>Examiner</b> YUN HAENG LEE	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/4/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1/4/2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5, 7 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims comprise the step of calculating a value for the cardiac output of the patient as a product of the measured velocity time integral and the estimated cross sectional area of the heart valve. However, it is well known, and it is also described in the specification, that the product

of the velocity time integral and the heart valve cross sectional area is the stroke volume, not the cardiac output. For the purposes of the present Office Action, it will be assumed that Applicant meant to calculate the cardiac output using the product of the velocity time integral and the heart valve cross sectional area.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pat. No. 6,565,513) in view of Nidorf et al. (J Am Coll Cardiol 1992;19:983-8).

Regarding claim 1, Phillips discloses a method of determining the cardiac output of a patient, the method comprising the steps of:

measuring the velocity time integral of blood flowing from the heart of the patient (col. 2 line 66);

measuring a heart valve diameter (col. 2 line 66); and

calculating a value for the cardiac output of the patient using the velocity time integral and the heart valve diameter (col. 3 lines 1-2).

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The calculating step would inherently comprise the step of calculating a value for the cardiac output of the patient using a product of the velocity time integral and the cross sectional area of the heart valve according to the formula relating these variables.

Nidorf et al. teaches of measuring the patient's height and calculating an estimate for the cross sectional area of the heart valve based on a single variable formula wherein the single variable is the patient's height (see Table 1). Nidorf et al. further teaches that height offers a simple yet accurate means of assessing the normalcy of cardiac dimensions. Therefore, it would have been obvious to one of ordinary skill in the art to measure the patient's height and calculate an estimate for the cross sectional area of the heart valve based on a single variable formula wherein the single variable is the patient's height, and use the estimate for the cross sectional area of the heart valve to calculate a value for the cardiac output of the patient in Philips.

Regarding claims 2, 3 and 11, see the Methods section of Nidorf et al.

Regarding claim 4, Nidorf et al. further disclose calculating the cardiac output using the aortic annular (see Table 1).

Regarding claim 5, Nidorf et al. further disclose the claimed formula in Table 1.

Regarding claim 7, the claimed formula is a simple mathematic derivation from the formula given in Table 1 of Nidorf et al. Therefore, it would have been obvious to one of

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ordinary skill in the art to derive and use the claimed formula instead of the formula given in Table 1 of Nidorf et al. Alternatively, it would have been obvious to one of ordinary skill in the art to derive and use the claimed formula since Nidorf et al. teaches that height relates linearly with cardiac dimensions and pulmonary annular diameter is a cardiac dimension.

Regarding claims 9 and 10, see the above discussions.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUN HAENG LEE whose telephone number is (571)272-2847. The examiner can normally be reached on M-Th 10-8.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/  
Supervisory Patent Examiner, Art Unit 3766

Carl H. Layno  
Supervisory Patent Examiner  
Art Unit 3766

/YHL/